Appendix 1: 510(k) Summary of Safety and Effectiveness

OCT 0 8 2002

K022565

Statement	Information supporting claims of substantial equivalence, as defined under the Federal Food, Drug and Cosmetic Act, respecting safety and effectiveness is summarized below. For the convenience of the Reviewer, this summary is formatted in accordance with the Agency's final rule "...510(k) Summaries and 510(k) Statements..." (21 CFR §807) and can be used to provide a substantial equivalence summary to anyone requesting it from the Agency.
Device description	The *Telstar*™ Biplane Digital Imaging System [TIS] is a digital fluoroscopic system providing bi-plane fluoroscopic clinical images of both patients and medical devices during conventional and magnetic procedures.
Intended use	Provides the utility of fluoroscopic imaging of vascular systems for applications including vascular angiography and electrophysiology (EP) studies. This x-ray system may be used stand-alone, or in conjunction with an associated Stereotaxis Magnetic Navigation System.
Substantial equivalence	The TIS is a modification of the *Telstar*™ Biplane Digital Imaging System originally cleared under K013484. The modifications described herein do not affect the intended use of the device or alter the fundamental scientific technology associated with the device.
Technological characteristics	The TIS provides visualization through standard fluoroscopy.

Continued on next page

Appendix 1: 510(k) Summary of Safety and Effectiveness, Continued

Device comparisons – Imaging

The following clarifies the modifications to the Telstar Biplane Digital Imaging System cleared under K013484.

Device Characteristics	Current TIS (K013484)	Modified TIS
Imaging	Fluoroscopic	Fluoroscopic
Pulsed fluoro	7.5, 15, 30 pulses/sec	7.5, 15, 30 pulses/sec
Pulsed cardiac	15, 30 pulses/sec	15, 30 pulses/sec
X-ray tube assembly	Rotating anode	Rotating anode
Image intensifier	Yes	Yes
Monitor	Quad 15"	Quad 15"
Operating modes	Fast Scan Fluoro (2x2 binning) only	Fast Scan Fluoro and Low Noise, High Sensitivity Fluoro (2x4 binning)
Frame rate	Same	Same

Physical testing

The TIS is designed and tested in compliance with the requirements of 21 CFR §1020.32 (Fluoroscopic Equipment).

Preclinical animal performance data

Preclinical performance data were provided in K013484. No new studies were required or necessary to support the modifications.

Clinical performance data

Clinical performance data were provided in K013484. No new studies were required or necessary to support the modifications.

Continued on next page

Appendix 1: 510(k) Summary of Safety and Effectiveness, Continued

Contact	Peter A. Takes, Ph.D., RAC Director, Clinical & Regulatory Affairs Stereotaxis, Inc. 4041 Forest Park Avenue St. Louis, Missouri 63108 Ph. 314-615-6964 Fax 314-615-6912
Date	August 1, 2002

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Peter A. Takes, Ph.D., RAC
Director, Clinical & Regulatory Affairs
Stereotaxis, Inc.
4041 Forest Park Avenue
ST LOUIS MO 63108

AUG 2 0 2013

Re: K022565
Trade/Device Name: Telstar Biplane Digital Imaging System
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: JAA
Dated: September 6, 2002
Received: September 9, 2002

Dear Dr. Takes:

This letter corrects our substantially equivalent letter of October 8, 2002.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Appendix 2: Statement of Intended Use

Statement

Indications for Use Statement:

510(k) Number: K022565

Device Name: Telstar™ Biplane Digital Imaging System [TIS]

Indications for Use: The Telstar™ Biplane Digital Imaging System provides the utility of fluoroscopic imaging of vascular systems for applications including vascular angiography and electrophysiology (EP) studies. This x-ray system may be used stand-alone, or in conjunction with an associated Stereotaxis Magnetic Navigation System.

Prescription Use ✓

David A. Lepmann
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K022565